

RCE & Amendment
Serial No.: 10/612,784
Attorney Docket No.: ORW01-GN004

REMARKS

Introductory Comments

Claims 1, 2, 4-6, 14, 15, 27-32, 37-39, 109, and 110 are pending in the present application. Claims 38 and 39 have been withdrawn in light of the previous restriction requirement. Claims 1 and 27 have been amended. Claims 3, 7-13, 16-26, 33-36, and 40-108 have been cancelled. Claims 109 and 110 have been newly added. A Request for Continued Examination is filed concurrently herewith. Reconsideration of the application is respectfully requested.

April 11, 2007 Office Action

35 U.S.C. §102 Rejections

Claims 27-36, 40-42, 46, 47, 51, 54-66, 71-78, and 82-87 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by German Published Patent Application No. DE 197 16 051 to Kluber ("Kluber"). This ground of rejection is moot with respect to claims 34-36, 40-42, 46, 47, 51, 54-66, 71-78, and 82-87, but has been overcome as to claims 27-32 by the amendments to claim 27.

Claim 27 has been amended, in part, to clarify that an acetabular cup assembly includes a two-piece structure comprising an acetabular cup permanently mounted to the patient's pelvis and an acetabular liner having mating features to releasably engage corresponding mating features of the acetabular cup. In contrast, the device of Kluber is directed to a single-piece cemented cup with no modularity. Specifically, Kluber has no application in revision acetabular arthroplasty or with a system that is modular (i.e., using a replaceable socket liner) as recited in claim 27. Therefore, the amendments to claim 27 clearly distinguish this claim from the structures of Kluber and therefore claim 27 is in condition for allowance, as well as the claims that depend therefrom.

It should also be noted that claim 27 includes the limitation requiring the semiannular augment to include at least one *integrated* fastener. Nothing in Kluber discloses such a feature. Instead, Kluber relies on separate screws to mount the securing

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ring to the socket component.^{1,2} What is required for anticipation is that the disclosure place those skilled in the art in possession of what is claimed.³ But Kluber certainly does not place those skilled in the art in possession of any augment with an integrated fastener as cited in claim 27.

Finally, as pointed out in the Office action, Kluber discloses that the PLLA is transformed into flexible native connective tissue, which the Examiner has interpreted as scar tissue. In direct contrast, Applicant claims an augment that does not form scar tissue, as the materials comprising the augment eventually dissolve completely so that no further support is provided to prevent dislocation after dissolution. Simply put, Applicant is claiming an augment that dissolves completely and does not form scar tissue, which is precisely the opposite of what Kluber teaches. In fact, the Office action itself concludes that those skilled in the art *would have wanted scar tissue formation*, which is in direct contrast with what Applicant is claiming. Support for Applicant's amendment is found at paragraphs [0041-0042].⁴ In view of the foregoing, it is respectfully submitted that claim 27 is in condition for allowance as Kluber fails to disclose each and every one of the limitations of this claim. Likewise, claims 28-32 that depend from claim 27 are also in condition for allowance at least for the same reasons as claim 27. Reconsideration and withdrawal of the rejections of record for claims 27-36, 40-42, 46, 47, 51, 54-66, 71-78, and 82-87 are respectfully requested.

35 U.S.C. §103 Rejections

Claims 1-15, 19-26, 37, 43-45, 48-50, 52-68, 71, 72, 79, and 88 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious in view of German Published Patent Application No. DE 197 16 051 to Kluber ("Kluber"). This ground of rejection is moot with respect to claims 3, 7-13, 19-26, 43-45, 48-50, 52-68, 71, 72, 79, and 88, but has

¹ See M.P.E.P. § 2131 "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

² See M.P.E.P. § 2131 "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

³ See *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (in order to anticipate, "the [prior art] reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it").

⁴ It should be noted that in paragraph [0042] Applicant distinguishes resorbable augments that completely go away, from augments 26 that could be formulated so as to be replaced by tissue (such as scar-tissue).

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been overcome as to claims 1, 2, 4-6, 14, 15, and 37 by the amendments to claims 1 and 27.

Both claims 1 and 27 have been amended, in part, to clarify that an acetabular cup assembly includes a two-piece structure comprising an acetabular cup permanently mounted to the patient's pelvis and an acetabular liner having mating features to releasably engage corresponding mating features of the acetabular cup. In contrast, the device of Kluber is directed to a single-piece cemented cup with no modularity. Specifically, Kluber has no application in revision acetabular arthroplasty or with a system that is modular (i.e., using a replaceable socket liner) as recited in claims 1 and 27. Therefore, the amendments to claims 1 and 27 clearly distinguish these claims from the structures of Kluber and therefore claims 1 and 27 are in condition for allowance, as well as the claims that depend therefrom.

It should also be noted that claim 27, from which claim 37 depends, includes the limitation requiring the semiannular augment to include at least one *integrated* fastener. The Examiner opines, as to claim 67, that snap-on retention members (integrated fasteners) would have been obvious to those skilled in the art. The Examiner then incorrectly concludes that it is up to Applicant to show some advantage, particular purpose, or solve a stated problem by using snap-on retention members, but cites no legal support for this conclusion.⁵ It is not Applicant's burden, however, to show nonobviousness in the absence of a *prima facie* case of obviousness. In the instant case, Kluber relies on separate screws to mount the securing ring to the socket component and the Examiner has cited to no prior art disclosing resorbable integrated fasteners. Simply put, nothing in Kluber would lead one skilled in the art to use an integral fastener.

Finally, as pointed out in the Office action, Kluber discloses that the PLLA is transformed into flexible native connective tissue, which the Examiner has interpreted as scar tissue. In direct contrast, Applicant claims an augment that does not form scar

⁵ See M.P.E.P. § 2144.03 ("As the court held in *Zurko*, an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. Id. at 1385, 59 USPQ2d at 1697. See also *In re Lee*, 277 F.3d 1338, 1344-45, 61 USPQ2d 1430, 1434-35 (Fed. Cir. 2002) (In reversing the Board's decision, the court stated "'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation.... The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies.").

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tissue, as the materials comprising the augment eventually dissolve completely so that no further support is provided to prevent dislocation after dissolution. Simply put, Applicant is claiming an augment that dissolves completely and does not form scar tissue, which is precisely the opposite of what Kluber teaches. In fact, the Office action itself concludes that those skilled in the art *would have wanted scar tissue formation*, which is in direct contrast with what Applicant is claiming.^{6,7} Support for Applicant's amendment is found at paragraphs [0041-0042].⁸ In view of the foregoing, it is respectfully submitted that claims 1 and 27 are in condition for allowance as Kluber fails to disclose or suggest each and every one of the limitations of these claims. Likewise, claims 1, 2, 4-6, 14, 15, 28-23 and 37-39 that depend from either claim 1 or 27 are also in condition for allowance at least for the same reasons as claims 1 and 27. Reconsideration and withdrawal of the rejections of record for claims 1-15, 19-26, 37, 43-45, 48-50, 52-68, 71, 72, 79, and 88 are respectfully requested.

Newly Added Claims

Claims 109 and 110 have been newly added. Each claim recites an acetabular liner and a semiannular augment, something clearly distinguishable from Kluber. In the context of claim 109, as previously applied to claim 22 for example, the Examiner's reliance on M.P.E.P. § 2144.04 IV (C) for the proposition that those skilled in the art would have made the augment of Kluber into multiple, separate parts is misplaced. The portion of the M.P.E.P. cited by the Examiner, which summarizes *In re Dulberg*, is inapposite to the instant situation of a single component allegedly cut into multiple pieces.

In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) involved a patent application and corresponding claims for lipstick holder with a removable cap that were rejected in view of prior art showing a lipstick holder where the cap was "press fitted" onto the holder and therefore not manually removable. The court held that "if it

⁶ See M.P.E.P. § 2145, X, D2 ("It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)")

⁷ See M.P.E.P. § 2144.05, III ("A *prima facie* case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997).")

⁸ It should be noted that in paragraph [0042] Applicant distinguishes resorbable augments that completely go away, from augments that could be formulated so as to be replaced by tissue (such as scar-tissue).

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were considered desirable for any reason to obtain access to the end of [the prior art's] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose." This fact pattern is clearly distinguishable from the instant facts in that *In re Dulberg* dealt with prior art comprising to two completely separate and clearly distinguishable components that were mounted to one another. This is in stark contrast to Kluber that relates only to a single ring with no distinguishable component parts. To be sure that this distinction is material, the CCPA used the term "removable" as opposed to "separable" when discussing the prior art in *In re Dulberg*, which was indicative of a situation where components were originally distinct from one another. This same "removable" language could not have been used in an instance where single part was arbitrarily cut or otherwise artificially broken into pieces. Thus, *In re Dulberg* provides insufficient basis for the conclusory assertion that it would be obvious to those skilled in the art to cut apart any single component.

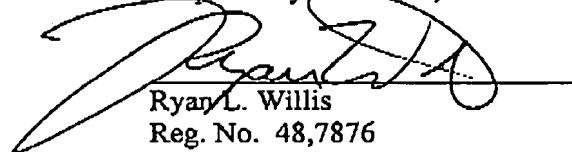
Conclusion

In light of the foregoing, it is respectfully submitted that claims 1, 2, 4-6, 14, 15, 27-32, 37-39, 109, and 110, now pending, are patentably distinct from the references cited and are in condition for allowance. Reconsideration and withdrawal of the rejections of record are respectfully requested.

The Commissioner for Patents is hereby authorized to charge any additional fees that may be required by this paper, or to credit any overpayment to Deposit Account 50-3072.

In the event that the Examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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